NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE MERCK & CO., INC. SECURITIES, DERIVATIVE & "ERISA" LITIGATION	:	**MDL No. 1658 (SRC)**
_____	:	**Civil Action No. 05-1151 (SRC)**
THIS DOCUMENT RELATES TO: THE CONSOLIDATED DERIVATIVE ACTION	:	**Civil Action No. 05-2368 (SRC)**
	:	**OPINION**

CHESLER, District Judge

This matter comes before the Court upon shareholder Plaintiffs' motion for leave to amend the Verified Consolidated Shareholders' Derivative Complaint ("Complaint"). (Docket item no. 50.) The Court had previously dismissed the Complaint by Order of May 5, 2006. (Docket item no. 31.) Plaintiffs appealed the Court's ruling denying them leave to amend the Complaint to add allegations based on discovery conducted after this lawsuit was initiated. For reasons set forth in an opinion published at 493 F.3d 393 (3d Cir. 2007), the Third Circuit Court of Appeals reversed that ruling and remanded the case to this Court for consideration of the legal sufficiency of an amended pleading that includes the additional information. The proposed Verified First Amended Consolidated Shareholders' Derivative Complaint ("proposed Amended Complaint") would add allegations intended to bolster Plaintiffs' claims that their failure to make a pre-suit demand on the Board of Directors (the "Board" or "Directors") of Merck & Co., Inc.

("Merck") must be excused as futile. Nominal defendant Merck and the individual defendants, comprising various present and former Merck executives and/or directors,[1] oppose the motion. (For purposes of simplicity, the Court will collectively refer to all defendants as "Merck".) Pursuant to Federal Rule of Civil Procedure 78, the Court rules on this motion based on the papers submitted by the parties.

For the reasons that follow, the Court denies Plaintiffs' motion. The Court will not permit amendment of the pleading on the grounds that the proposed Amended Complaint would fail to state a claim upon which relief may be granted. Because the Court has already determined that the Complaint lacks legal sufficiency, and its previous ruling that the claims pled in the Complaint must be dismissed with prejudice was not appealed, this action must be closed.

I. BACKGROUND

The consolidated stockholders' derivative litigation before the Court arises out of financial harm sustained by Merck allegedly as a result of the continued sale and marketing of the prescription drug Vioxx, which was ultimately withdrawn from the market. Merck moved to dismiss the Complaint for failure to plead with the requisite particularity why making a demand on the Board of Directors in place on March 11, 2004, when the first shareholder derivative action was filed, would have been futile. Plaintiffs moved for leave to amend the Complaint to

[1] The individual defendants named in the action are: H. Brewster Atwater, Jr., Derek Birkin, Lawrence A. Bossidy, William G. Bowen, Erskine B. Bowles, Johnnetta B. Cole, William M. Daley, Lloyd C. Elam, Charles E. Exley, Jr., Niall FitzGerald, Kenneth C. Frazier, Raymond V. Gilmartin, William B. Harrison, Jr., Richard C. Henriques, Jr., William N. Kelley, Shelly Lazarus, Judy C. Lewent, Mary M. McDonald, Heidi G. Miller, Edward M. Scolnick, Thomas E. Shenk, Anne M. Tatlock, Samuel O. Thier, Dennis Weatherstone, Wendell P. Weeks and Peter C. Wendell.

cure its deficiencies by adding allegations based on documents and information obtained by Plaintiffs in discovery after this suit was initiated. (Hereinafter, the material obtained in discovery will be referred to as "after-acquired information".) By Order of May 5, 2006, the Court granted the motion to dismiss on the grounds that the Complaint failed to plead demand futility with particularity, as required by the Federal Rules of Civil Procedure and applicable caselaw. It denied the motion for leave to amend on the grounds that Federal Rule of Civil Procedure 23.1 would not permit Plaintiffs to rely on the after-acquired information to bolster their claims of demand futility. The Court's reasoning is set forth in an accompanying May 5, 2006 Opinion. (Docket item no. 30.)

Plaintiffs appealed the Court's ruling on their motion for leave to amend the Complaint. The Third Circuit Court of Appeals held that while the general rule is that discovery may not be used to supplement demand futility allegations, it did not apply in the case at bar. The Court of Appeals reasoned that the limited exception was appropriate because the parties had engaged in discovery pursuant to a June 27, 2005 stipulated discovery agreement, which did not restrict the manner in which the after-acquired information could be used. In light of the liberal pleading standards of Federal Rule of Civil Procedure 15 and the voluntary and unrestricted nature of the discovery stipulation, the Third Circuit held that this Court erred as a matter of law in refusing to consider the additional allegations proposed by Plaintiffs to bolster their theory that demand on the Board would have been futile because a majority of the Directors faced a substantial likelihood of personal liability . The Third Circuit, however, declined to examine the substance and viability of an amended complaint. Instead, it deferred to this Court to analyze whether demand futility had been sufficiently pled, upon consideration of the proposed Amended

Complaint – meaning the allegations previously evaluated by the Court together with the additional proposed allegations based on after-acquired information. Accordingly, this Court's ruling on the motion for leave to amend the Complaint was reversed, and the matter was remanded.

The Court notes that Plaintiffs did not appeal the its ruling with regard to the legal sufficiency of the Complaint. Thus, the Court's determinations on all issues raised in Merck's motion to dismiss remain the law of the case. Cowgill v. Raymark Indus., Inc., 832 F.2d 798, 802 n.2 (3d Cir. 1987). On remand from the Court of Appeals, this case presents a narrow question, carefully framed by the Third Circuit. Though available in the published opinion, the instruction bears repeating:

> In light of the business judgment presumption as well as the standard for demand futility in board inaction cases, the District Court on remand must inquire into whether the after-acquired information, as well as the information contained in the initial complaint, supports the position that the Board recklessly ignored a well-established link between VIOXX [sic] and increased cardiovascular risk to establish that the Board acted egregiously or in bad faith. Because the plaintiffs do not challenge the District Court's conclusion that the original complaint's allegations were "patently conclusory," the question before the District Court will be whether the additions permitted by virtue of this opinion will transform the complaint from patently conclusory to a complaint that establishes to a sufficient degree of particularity that the March 2004 Directors approved, participated in, or caused Merck to make strategic decisions regarding the marketing of VIOXX [sic].

In re Merck & Co., Inc. Sec., Derivative & ERISA Litig., 493 F.3d at 403.

The factual background of this case is familiar to the parties and is, moreover, set forth in this Court's May 5, 2006 opinion and the Third Circuit's opinion at 493 F.3d 393. The Court will not repeat those facts here, nor will it repeat its summary of the Complaint's allegations

relevant to demand futility. The proposed Amended Complaint sets forth allegations pled in the original Complaint, adding averments based on the after-acquired discovery.

Insofar as the new allegations are relevant to this motion,[2] they identify a number of Board meetings that were convened during the time period spanning 2000 to 2003. Plaintiffs aver that the Board discussed research results and articles concerning the cardiovascular risks associated with Vioxx. They also identify and describe presentations given to the Board by Merck scientists and executives during that time period regarding Vioxx's safety profile. Additionally, the proposed Amended Complaint states that the Board was well-informed of Vioxx's commercial success and that it endeavored to exploit its performance to make money for Merck.

Plaintiffs allege that the March 2004 Directors were aware of the results of several studies - namely, Study 090, the VIGOR study[3], the ADVANTAGe[4] study and the Topol study,[5] which they contend demonstrated significant increases in cardiovascular events in Vioxx patients.

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[2] Because certain documents underlying the additional averments were produced by Merck as confidential, pursuant to a protective order, many of the additional allegations are redacted from the publicly available proposed Amended Complaint. The Court has carefully reviewed the entire proposed Amended Complaint filed under seal. At times, its description of the facts pled has been kept intentionally general, to safeguard the information deemed by the parties to be commercially sensitive.

[3] This study and its results are discussed in the May 5, 2006 Opinion of this Court.

[4] Assessment of Differences between Vioxx and Naproxen to Ascertain Gastrointestinal Tolerability and Effectiveness, an internal Merck study completed in April 2000.

[5] This study, conducted by Drs. Eric J. Topol, Debabrata Mukherjee and Steven E. Nissen at the Cleveland Clinic, is discussed in the May 5, 2006 Opinion's discussion of an August 22, 2001 article published in the Journal of the American Medical Association ("JAMA") reporting on this study.

Plaintiffs allege that the Board was also aware of Dr. Garret Fitzgerald's theory that Vioxx caused heart attacks and strokes because it suppressed prostacyclin, a compound that inhibits platelet aggregation (i.e., helps to reduce blood clotting) but did not inhibit thromboxane, a compound that stimulates platelet aggregation (i.e., increases blood clotting). (This theory is referred to as the "prostacyclin hypothesis".) Moreover, the allegations charge the Board with fabricating the "naproxen hypothesis" - which attributed the study results to cardio-protective properties of naproxen, another non-steroidal anti-inflammatory drug - even though all the Directors knew that it was not supported by clinical evidence or studies. Plaintiffs point specifically to a Warning Letter from the Food and Drug Administration dated September 17, 2001, sent directly to Board chairman Raymond V. Gilmartin, that reprimanded Merck for misrepresenting the safety profile of Vioxx in promoting the drug, specifically by endorsing the unproven naproxen hypothesis as fact.

In addition to supplying detailed information about what the Board knew (based on matters discussed in meetings and information supplied or available to the Board through presentations and articles), the proposed Amended Complaint includes allegations about the Board's wrongdoing. Plaintiffs allege, based on documents obtained in the stipulated discovery, that the Directors possessed information about Vioxx, as set forth above and in the May 5, 2006 Opinion, discussed it among themselves and nevertheless continued to sell and promote Vioxx. The proposed Amended Complaint alleges that the Board approved aggressive marketing campaigns, including promoting the drug directly to consumers, despite knowing of the cardiovascular risks of Vioxx and the consequences to Merck of continuing to sell the drug. It charges the Board with authorizing Merck to disseminate information confirming the drug's

favorable cardiovascular safety profile.

In sum, Plaintiffs allege that the "Board knew by March 2000 about Vioxx's cardiovascular risks but continued to accelerate its marketing program and sell the drug despite this knowledge." (Proposed Am. Compl., ¶ 81) They allege that the Board acted egregiously in that its "conduct after March 2000 in continuing to allow the aggressive and relentless misleading overpromotion of Vioxx to the broadest universe of patients is indefensible." (Id., ¶ 141.) The proposed Amended Complaint contains more information than the Complaint did about what the Board knew about Vioxx, how they knew it and what the Directors allegedly did wrong. The question now is whether the proffered additional averments transform Plaintiffs' pleading from one that the Court has held is patently conclusory to one that satisfies the heightened pleading standards that apply to a shareholder derivative suit.

II. ANALYSIS

A. Legal Standards

Rule 15(a) of the Federal Rules of Civil Procedure governs motions for leave to amend a complaint. While Federal Rule of Civil Procedure 15(a) directs that leave to amend a complaint should be freely given, the Supreme Court has held that leave to amend should be denied based, among other reasons, for undue delay, bad faith, undue prejudice, and futility of the proposed amendment. Foman v. Davis, 371 U.S. 178 (1962). Defendants take the position that the instant motion should be denied because the proposed Amended Complaint would be futile.

When assessing the viability or futility of a proposed amendment, the Court applies the same analysis it would in a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6).

See In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1420 (3d Cir. 1997). In other words, an amendment would be futile if "the complaint, as amended, would fail to state a claim upon which relief could be granted." Id. at 1434. A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) may be granted only if, accepting all well-pled allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, a court finds that the plaintiff has failed to set forth fair notice of what the claim is and the grounds upon which it rests. Bell Atlantic Corp. v. Twombly, 127 S.Ct. 1955, 1965 (2007) (citing Conley v. Gibson, 355 U.S. 41, 47 (1957)). The Court, however, "need not credit unsubstantiated conclusions and bald assertions." Schuylkill Energy Res., Inc. v. Pa. Power & Light Co., 113 F.3d 405, 420 (3d Cir.), cert. denied, 522 U.S. 977 (1997). In evaluating a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court may consider the complaint, exhibits attached to the complaint, matters of public record, documents integral to or explicitly relied upon in the complaint and documents incorporated into the complaint by reference. Winer Family Trust v. Queen, 503 F.3d 319, 327 (3d Cir. 2007); Burlington Coat Factory, 114 F.3d at 1426.

A complaint will survive a motion under Rule 12(b)(6) if it states plausible grounds for plaintiff's entitlement to the relief sought. Bell Atlantic Corp., 127 S.Ct. at 1965-66 (abrogating Conley's standard that the "complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief"). In other words, it must contain sufficient factual allegations to raise a right to relief above the speculative level. Id. at 1965. The issue before the Court "is not whether plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence in support of the claims." Burlington Coat Factory, 114 F.3d at1420 (quoting Scheuer v. Rhodes,

416 U.S. 232, 236 (1974)).

In this case, because the claim under review asserts demand futility, the heightened pleading standard of Federal Rule of Civil Procedure 23.1 is triggered. Rule 23.1 requires that plaintiffs claiming demand futility must plead with specificity why their failure to make a pre-suit demand on a company's board of directors should be excused. Plaintiffs must allege particularized facts that support their assertion that, at the time the derivative lawsuit was filed, the sitting board would have been incapable of impartially evaluating a demand to bring suit. In re Prudential Ins. Co. Derivative Litig., 282 N.J. Super 256, 275 (App. Div. 1995).

Thus, while this matter comes before the Court on the procedural posture of a motion for leave to amend, the Court is tasked with reviewing the proposed amended Complaint for legal sufficiency, as it would had the matter been presented as a motion to dismiss. The Court, by reference to its May 5, 2006 opinion on Merck's motion to dismiss the Complaint, incorporates that opinion's extensive discussion of the requirements for adequately pleading demand futility under New Jersey law in this case.[6]

B. Discussion

The Court may grant Plaintiffs leave to file their proposed Amended Complaint if its allegations create a reasonable doubt that a majority of the Board, as constituted on March 11, 2004, was disinterested and independent, making it incapable of impartially considering a shareholder demand and thus rendering demand futile. In re PSE&G Shareholder Litig., 173 N.J.

[6] Merck is a New Jersey corporation. The substantive requirements of demand are therefore governed in this case by New Jersey law. Kamen v. Kemper Fin. Servs., Inc., 500 U.S. 90, 96-97 (1991). New Jersey looks to the law of Delaware for evaluating claims of demand futility. See, generally, PSE&G, 173 N.J. 258 (2002); Prudential, 282 N.J. Super 256 (App. Div. 1995).

258, 282 (2002); Rales v. Blasband, 634 A.2d 927, 930, 934 (Del. 1993) (articulating demand futility standard in cases alleging that board's wrongdoing consists of inaction rather than a challenged transaction). The question before the Court is whether the proposed Amended Complaint sufficiently pleads directorial interest based upon a substantial likelihood of personal liability faced by a majority of the Board. Id. at 936. As the Court stated in its May 5, 2006 opinion, a substantial likelihood of liability can be shown in those "rare cases" in which the board's conduct has been "egregious." Aronson v. Lewis, 473 A.2d 805, 815 (Del. 1984), overruled on other grounds by Brehm v. Eisner, 746 A.2d 244 (Del. 2000). Applying this standard to the shareholder derivative suit at bar, the Court must determine whether the proposed Amended Complaint's allegations can support Plaintiffs' position that the Board's failure to withdraw Vioxx from the market "is so far beyond that bounds of reasonable judgment that it seems essentially inexplicable on any ground other than bad faith." Parnes v. Bally Entm't Corp., 722 A.2d 1243, 1246 (Del. 1999).

The proposed Amended Complaint adds detail about information possessed by the Board regarding Vioxx's cardiovascular safety profile . Having the benefit of Board meeting minutes turned over in the stipulated document production, Plaintiffs have been able to plead with particularity that the Board discussed various matters relating to Vioxx, which the Court will not divulge with any specificity here to maintain the confidentiality of the information. Suffice it to say that the Merck Board, over the course of the several years preceding the filing of the first derivative suit on March 11, 2004, met as corporate boards typically do and that in various of those meetings, the Board was informed of the results of continuing Vioxx research and testing

being performed by both Merck scientists and non-Merck members of the scientific and medical communities.

Although the allegations have become more particularized that they were in the Complaint, the proposed Amended Complaint nevertheless fails to meet the high burden of pleading demand futility. The ultimate question of demand futility, as tailored by the Third Circuit to this case, is whether the proposed Amended Complaint "supports the position that the Board recklessly ignored a well-established link between VIOXX and increased cardiovascular risk to establish that the Board acted egregiously or in bad faith." 493 F.3d at 403. The answer is no. The proposed Amended Complaint meets neither of the analysis's two components – knowledge and reckless inaction.

The proposed Amended Complaint is specific about what the Board knew, but at best it succeeds in demonstrating that the Directors were aware of an active debate in the medical and scientific communities over whether a causal link between Vioxx and cardiovascular events (i.e., heart attack and stroke) existed. In evaluating the legal viability of the Amended Complaint, the Court is permitted to consider documents on which Plaintiffs have based their allegations. Burlington Coat Factory, 114 F.3d at 1426; see also In re Milestone Scientific Sec. Litig., 103 F.Supp.2d 425, 450 (D.N.J. 2000) (holding that although court may not generally consider material extrinsic to the complaint when evaluating a motion to dismiss, it "may properly refer to the factual allegations contained in other documents, such as documents referred to in the complaint and matters of public record if the claims in the complaint are based upon those documents.") Those documents reveal that evidence of the Vioxx link to heart attacks and strokes was mixed. Many of the studies cited by Plaintiffs as proof that Vioxx increased the risk

of cardiovascular events compared to other drugs were interpreted as unreliable or inconclusive. For example, the FDA concluded in a February 8, 2001 Advisory Committee Briefing Document that Study 090, which was submitted to the FDA by Merck, was of limited value due to its "population size, dose and duration". (Decl. of Robert H. Baron In Support of Defendants' Response In Opposition to Plaintiffs' Motion for Leave To Amend, dated Jan. 9, 2008 ("Baron Decl."), Ex. 7 at 17.) The August 22, 2001 JAMA article reporting on the Topol study observed: "The results of the VIGOR study can be explained by either a significant prothrombotic effect from rofecoxib or an anitthrombotic effect from naproxen (or conceivably both)." (Id., Ex. 18 at 957.) The article also deemed the VIGOR study inconclusive: "Because of the evidence for an antiplatelet effect of naproxen, it is difficult to assess whether the difference in cardiovascular event rates in VIGOR was due to a benefit from naproxen or to a prothrombotic effect from rofecoxib." (Id.) A May 2004 article published in the American Heart Association journal Circulation, cited in the proposed Amended Complaint, noted that the VIGOR study could not discern whether the greater incidence of heart attacks in patients taking Vioxx versus naproxen was due to a protective effect of naproxen or increased risk associated with a selective COX-2 inhibitor (coxib), e.g., Vioxx. (Id., Ex. 11 at 2068) It noted that "previous studies on the association between coxibs and [acute myocardial infarction] have provided conflicting results." (Id.) Following the VIGOR study, the FDA approved a modified package insert that stated that "the significance of the cardiovascular findings from these 3 studies (VIGOR and 2 placebo-controlled studies) is unknown." (Id., Ex. 9 at 12.)

The proposed Amended Complaint's source documents reveal the Board received reassurances from company executives and scientists that Vioxx was safe. Internal

communications, presentations and meeting minutes demonstrate that the Board was supplied with positive information about Vioxx, on which the Board relied. The Court has reviewed presentations given by three different Merck scientists who provided the Board with data that, the scientists concluded, demonstrated that there was no proven correlation between Vioxx and cardiovascular risk. (See Baron Decl., Ex. 3, 14, and 15 (filed under seal).) These reassurances further weaken Plaintiffs' demand futility theory, which maintains that the Board recklessly ignored the dangers of Vioxx. Even incorporating additional detail in their pleading, Plaintiffs do not overcome the fact that the Board was presented with credible, scientific information about the favorable safety profile of Vioxx. Courts considering the question of directors' personal liability have observed that "directors are entitled to rely on the honesty and integrity of their subordinates until something occurs to put them on suspicion that something is wrong." In re Baxter Int'l, Inc. Shareholders Litig., 654 A.2d 1268, 1270 (Del.Ch. 1995) (quoting Graham v. Allis-Chalmers Mfg. Co., 188 A.2d 125, 130 (Del. 1963)). They have held, in the context of derivative suits based on directors' failure to prevent employee wrongdoing, that only the directors' disregard of "obvious danger signs" may expose them to personal liability. Id. (quoting Graham, 188 A.2d at 130.) Plaintiffs in effect would have this Court believe that Board members, presented with evidence by Merck's corporate employees entrusted with evaluating the issue and managing its product, were required to ignore this advice in the face of contrary information about Vioxx. Only then, according to Plaintiff's theory, would the Board members be able to avail themselves of the business judgment rule. Such a result would turn the demand futility requirement on its head, expose corporate directors to unpredictable and extraordinary levels of personal liability and potentially cripple effective corporate management. Under the

business judgment rule, corporate directors are not required to exercise 20/20 hindsight where reasonable minds could differ.

The proposed Amended Complaint also fails to plead particularized facts regarding the Directors' participation in the alleged wrongdoing, that is, exactly how they were involved in the failure to halt or decrease the promotion and sale of Vioxx. The March 2004 Board consisted of 13 individuals: Merck President and Chief Executive Officer Raymond V. Gilmartin and 12 outside Directors.[7] An outside director is typically not involved in the day-to-day operations of a business, and Plaintiffs have not alleged that the outside Directors on the Board varied from this paradigm. In other words, the proposed Amended Complaint continues to suffer from the same deficiency that plagued the dismissed Complaint: It fails "to allege facts establishing that any of the outside directors were involved in the research, development, manufacturing or sale of Vioxx." (May 5, 2006 Opinion at 23.) Instead, the proposed Amended Complaint contains allegations that the Board "approved" and/or "authorized" marketing strategies and press releases promoting Vioxx despite the Board's awareness of research showing that the drug put a patient at an increased risk of cardiovascular event. These allegations alone, without specific averments about individual Directors' direct involvement in the challenged wrongdoing, do not cast doubt on the Directors' disinterestedness. See PSE&G, 173 N.J. at 290 ("A director is not be viewed as being 'interested' merely because he or she may have approved the challenged transaction . . . .").

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[7] The Court notes that the composition of the Board was not static throughout the time period discussed in this Opinion, that is, from the introduction of Vioxx to the market (May 19, 1999) to the filing of the first derivative lawsuit (March 11, 2004). However, the events analyzed are relevant to the demand futility question of whether a majority of the board sitting when the lawsuit was filed had a disabling interest. Eight of the 13 Directors on the March 2004 Board sat on the Merck Board throughout the entire period, and two others were on the Board since 2000.

Apart from failing to provide specific facts that directly implicate the Directors' involvement in the wrongdoing complained of in this lawsuit, the proposed Amended Complaint provides absolutely no basis on which to infer that the outside Directors engaged in conduct that exposed them to personal liability. Having obtained Board meeting minutes in the stipulated discovery, Plaintiffs have been able now to identify individual Directors who attended those meetings in which Vioxx was on the agenda. Cf. Prudential, 282 N.J. Super. at 277 (finding complaint's allegations of demand futility deficient because they did not "single out, among current or past directors, which directors participated in the alleged wrongdoing, which directors 'control' the board and which are, in turn, 'controlled'.") The Directors' attendance at Board meetings in which issues concerning Vioxx's cardiovascular safety profile and Merck's marketing of the product were discussed does not, without more, establish that a majority of them faced a substantial risk of personal liability.

Indeed, many of Plaintiffs' critical allegations of Board knowledge and inaction remain conclusory. Plaintiffs allege that Dr. Edward Scolnick,[8] President of Merck Research Laboratories during part of the relevant time period, and other Merck scientists knew that naproxen was not cardioprotective. They also allege that Merck scientists were urged by other leading scientists and doctors in the field to conduct further studies on the cardiovascular safety of Vioxx. The inference Plaintiffs believe should be drawn is that the Merck Board acted in bad faith by continuing to market a drug they knew was dangerous, all the while rejecting advice to conduct safety studies. The proposed Amended Complaint simply does not support this

[8] Dr. Scolnick served on the Board from 1997 to 2002 but was not a Director at the time the first derivative suit was filed. Therefore, any doubts as to his disinterestedness are not relevant to the Court's demand futility analysis.

inference because it fails to connect allegations that Merck employees ignored known safety risks to its conclusions that Merck Directors did also.

In evaluating whether the proposed Amended Complaint raises a reasonable doubt as to the Directors' disinterest, the Court must take into account the business judgment rule. Merck, 493 F.3d at 399-400. "[T]he business judgment rule provides directors with a powerful presumption that in making a business decision the directors of a corporation acted on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the company." Id. at 402 (internal citations and quotations omitted). Plaintiffs' allegations simply do not rebut that presumption.

The Court recognizes that there was abundant public discussion about the subject, and one might even conclude that the weight of information indicated that there were problems with Vioxx. However, the mix of information on the subject, the lack of consensus on the cause of an increased risk of thrombotic event in Vioxx users and the reassurances on which the Board relied prevent this Court from concluding, as Plaintiffs urge, that the Board turned a blind eye to the evidence and instead willfully fabricated an untenable explanation (the hypothesis that naproxen is cardioprotective) for the results of the VIGOR study. The Court's inquiry on this motion is limited to whether the proposed Amended Complaint adequately pleads demand futility, an inquiry that must be guided by the presumption afforded to the Directors' actions, or failure to act, by the business judgment rule. The role of this Court is not to give an opinion as to whether the conduct of Merck & Co., Inc. with regard to Vioxx is to be lauded or held up as a model of responsible corporate management insofar as the company handled public disclosures about the product, its consumer marketing campaign, and other business activities. Its role is merely to

determine whether the allegations of the proposed Amended Complaint are sufficient to demonstrate that the Merck Board "recklessly ignored a well-established link between Vioxx and increased cardiovascular risk." 493 F.3d at 403.

Upon review of the proposed Amended Complaint, together with the documents on which the allegations are based, this Court finds that Plaintiffs have not met their burden of raising a reasonable doubt as to the March 2004 Board's disinterestedness. In other words, on these facts, the Court cannot conclude that the Board's failure to eliminate or reduce Merck's promotion and sale of Vioxx is the type of bad faith inaction that should fall outside the protection of the business judgment rule. Cf. In re Tower Air, Inc., 416 F.3d 229, 239 (3d Cir. 2005) (suggesting that airline company directors' passivity in response to reports of problems with aircraft maintenance may amount to bad faith).

Plaintiffs' position that the Board could not have exercised its disinterested business judgment in responding to a demand seems to be based on a theory that a director may be exposed to a substantial risk of personal liability for a failure to take corrective action upon notice of a possible problem. Plaintiffs sum up their theory of disabling director interest as follows: "When the directors here received test results and scientific support which put them on notice of the risk that Vioxx caused heart attacks or strokes, they could no longer claim ignorance of this risk, or blindly dismiss these serious risks on the reliance of an unsupported and unsupportable 'naproxen theory' which the FDA described as entirely hypothetical." (Pl. Reply Br. at 3.) This extraordinarily low standard for triggering director liability finds no support in the law and, moreover, contravenes the well-established business judgment rule. Plaintiffs cite, in the proposed Amended Complaint and the briefs, this Court's opinion in the securities fraud

action relating to Vioxx, reported at 483 F.Supp.2d 407 (D.N.J. 2007). They appear to be conflating the legal standard applicable to determining when a shareholder's securities fraud claim accrues (the inquiry notice standard) with the law governing when a shareholder's failure to make a demand on a corporate board should be excused such that the shareholder can pursue a claim belonging to the corporation.

Plaintiffs' other attempts to bolster their demand futility claims also fail. They emphasize that the Directors hold various advanced degrees and that four of them even possess extensive backgrounds and training in bioscience and medicine. This statement about the sophistication of the Directors sheds no light on how their failure to halt the sale of Vioxx, or at least to scale back its promotion so as to not market the drug to at-risk patients, can only be explained as bad faith conduct and therefore outside the bounds of the business judgment rule, as Plaintiffs allege. Nor do allegations relating to the Board's attention to the commercial performance of Vioxx.

In short, the deficiencies of the Complaint's demand futility pleading remain uncured in the proposed Amended Complaint. Facts alleged in a complaint must be sufficient to overcome the presumption that directors are disinterested and independent and act with sound business judgment. Prudential, 282 N.J. Super. at 275. Plaintiffs inserted into the proposed Amended Complaint particularized allegations about what the Board knew, in an attempt to demonstrate that the Board's inaction was fueled by bad faith. At best, however, the allegations and underlying documents show that the Board had knowledge of a contest between explanations for increased cardiovascular risk in patients taking Vioxx compared to patients taking other non-steroidal anti-inflammatory drugs. The new allegations, while more specific than those in the dismissed Complaint, do not transform the pleading into one that warrants Plaintiffs' use of the

deliberately limited remedy of the derivative action. Kamen, 500 U.S. at 98; Landy v. Fed. Deposit Ins. Corp., 486 F.2d 139, 146 (3d Cir. 1973).

Thus, the Court holds that, upon consideration of the proposed Amended Complaint in its entirety and the documents integral to or explicitly relied upon in pleading, the proposed Amended Complaint fails to state a claim upon which relief can be granted. Permitting the amendment Plaintiffs proffer would be futile. Accordingly, the Court will not grant Plaintiffs leave to amend the Complaint.

III. CONCLUSION

For the foregoing reasons, the Court denies Plaintiffs' motion for leave to amend the Complaint. As the Court has previously dismissed the Complaint, a ruling which binds Plaintiffs, this action must be closed. An appropriate form of Order will be filed.

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

Dated: June 17, 2008